

Abacavir/Lamivudine 600/300 APOTEX Tablet

Contains the active ingredients abacavir (as sulfate) and lamivudine

Consumer Medicine Information

PATIENTS TAKING ABACAVIR AND LAMIVUDINE COMBINATION TABLETS, WHICH CONTAINS ABACAVIR, MAY DEVELOP A HYPERSENSITIVITY REACTION (SERIOUS ALLERGIC REACTION) WHICH CAN BE LIFE-THREATENING IF TREATMENT WITH THIS MEDICINE IS CONTINUED. CONTACT YOUR DOCTOR IMMEDIATELY FOR ADVICE ON WHETHER YOU SHOULD STOP TAKING ABACAVIR AND LAMIVUDINE COMBINATION TABLETS 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 GENERAL ILL FEELING**

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

THERE IS AN ALERT CARD INCLUDED IN THE ABACAVIR AND LAMIVUDINE 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 AND LAMIVUDINE.

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about this medicine. 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 this medicine 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 this medicine is used for

This medicine contains the active ingredients abacavir (as sulfate) and lamivudine which belong to a group of medicines called antiretrovirals.

Abacavir and lamivudine combination tablets are used together with other antiretrovirals to slow down the progression of human immunodeficiency (HIV) infection, which can lead to Acquired Immune Deficiency Syndrome (AIDS) and other related illnesses (e.g. AIDS-related Complex or ARC).

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

Abacavir/Lamivudine does not reduce the risk of passing the infection to others. 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.

While taking abacavir/lamivudine 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.

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

Your doctor may have prescribed this medicine for another reason.

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

There is no evidence that this medicine is addictive.

This medicine should not be used in children aged less than 12 years who weigh less than 40 kg, for whom dosage recommendations vary based on body weight.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- any medicine containing abacavir or lamivudine
- any of the ingredients listed at the end of this leaflet

Do not breastfeed if you are taking this medicine.

Abacavir/Lamivudine may pass into breast milk and there is a possibility that your baby may be affected. Your doctor will discuss the risks and benefits involved.

Do not take this medicine if you have a serious liver disease.

This medicine may not be suitable for you.

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.

Special Warning

Hypersensitivity reaction (serious allergic reaction):

About 5 in every 100 patients who are treated with abacavir and lamivudine combination tablets develop a hypersensitivity reaction to the active ingredient abacavir.

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 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 and lamivudine combination 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 and lamivudine combination 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 and lamivudine combination tablets, NEVER take abacavir and lamivudine or any other medicinal product containing abacavir again as within hours you may experience life-threatening lowering of your blood pressure or death.

Occasionally life-threatening hypersensitivity reactions have occurred when abacavir and lamivudine combination tablets were 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 and lamivudine combination tablets were restarted in patients who had no symptoms of hypersensitivity before stopping.

If you have stopped taking abacavir and lamivudine combination tablets for any reason it is important that you contact your doctor before restarting. This is especially 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 and lamivudine combination tablets again. It is important that you follow this advice.

If you are hypersensitive to abacavir and lamivudine combination tablets you should return all your unused abacavir and lamivudine combination tablets to your doctor or pharmacist for proper disposal.

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 or have had any of the following medical conditions:

- hepatitis B
- a heart attack or you are considered at a high risk of having a heart attack

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Do not take this medicine until you and your doctor have discussed the risks and benefits involved.

Tell your doctor if you have recently been vaccinated or plan to get a vaccination.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

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

Some medicines may interact with abacavir and lamivudine. These include:

- trimethoprim-sulphamethoxazole, (an antibiotic used to treat PCP - Pneumocystis carinii pneumonia or toxoplasmosis)
- sorbitol-containing medicines (usually liquids) used regularly

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.

These medicines may be affected by abacavir/lamivudine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to take this medicine

Follow carefully all directions given to you by your doctor.

Their instructions may be different to the information in this leaflet.

If you do not understand the directions, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much of this medicine you should take.

This will depend on your condition and whether you are taking any other medicines.

The normal dose for adults and adolescents is one tablet once a day.

How to take it

Abacavir/Lamivudine tablets should be swallowed whole with water.

Abacavir/Lamivudine does not have to be taken with food.

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 for

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.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time 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.

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.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of

this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking this medicine

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, remind your doctor and pharmacist that you are taking this medicine.

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 or start to breastfeed 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 your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Tell your doctor if you plan to have any vaccinations or immunisations.

Things you must not do

Do not take this medicine 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 stopped taking abacavir and lamivudine combination 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 other illness. In some cases, your doctor will ask you to restart abacavir and lamivudine combination tablets where medical care can be readily accessed by yourself or others.

If you have hepatitis B infection, you should not stop abacavir and lamivudine combination tablets 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 when driving or operating machinery until you know how this medicine affects you.

There are no studies on the effects of abacavir/lamivudine on the ability to drive and use machines.

However, you should consider the state of your health and the possible side effects of abacavir and lamivudine combination tablets before considering driving or using machines.

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, even if the problem is not listed in this leaflet.

All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Hypersensitivity Reaction

A hypersensitivity reaction (serious allergic reaction) has been reported in about five in every hundred patients who have been treated with abacavir/lamivudine. This is described in the

section "Special Warning" under "Before You Take This Medicine", of this leaflet.

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

As this medicine contains both abacavir and lamivudine, the side effects reported for each of these have been combined.

Tell your doctor if you notice any of the following:

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

Tell your doctor as soon as possible if you notice any of the following:

- increases in enzymes produced by the liver
- anaemia (low red blood cell count) – you may have symptoms of tiredness or breathlessness.
- neutropenia (low white blood cell count) – 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.
- reduction in the number of platelets (blood cells important for blood clotting)
- breakdown of muscle tissue, increases of an enzyme called amylase
- inflammation of the pancreas (pancreatitis)
- serious skin reactions
- severe anaemia

Changes in fat distribution have been reported in association with antiretroviral medicines. These may include:

- loss of fat from legs, arms and face
- increased fat in the abdomen (belly) and other internal organs, breasts and back of the neck

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 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.

The above list includes serious side effects that may require medical attention.

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, or similar medicines (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.
- symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin
 - 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 and 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 occur in some patients.

Some of these side effects, such as changes to your lipid and blood glucose levels, can only be found when your doctor does tests from time to time to check your progress.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C.

Do not store your medicine, 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 this medicine 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 Abacavir/Lamivudine 600/300 APOTEX Tablets looks like

600/300 mg Tablet

Orange coloured, modified capsule-shaped, biconvex film-coated tablet with engraved "APO" on one side and "600/300" on the other side. AUST R 239753. AUST R 239757.

Available in blister packs or bottles of 30 tablets.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 600 mg of abacavir (as sulfate) and 300 mg lamivudine as the active ingredients.

It also contains the following inactive ingredients:

- microcrystalline cellulose
- croscarmellose sodium
- colloidal anhydrous silica
- magnesium stearate
- hypromellose
- macrogol 8000
- titanium dioxide
- sunset yellow FCF aluminium lake

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Sponsor

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

Australia

Tel: (02) 8877 8333

Web: www1.apotex.com/au

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