

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

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about abacavir and lamivudine combination tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is Abacavir/Lamivudine 600/300 APOTEX tablets. It contains the active ingredients abacavir (as sulfate) and lamivudine.

They belong to a group of medicines called antiretrovirals.

They are also available as separate medicinal products: Ziagen (abacavir) and 3TC (lamivudine).

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).

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.

How it works

Abacavir and lamivudine combination tablets do not cure AIDS or kill the HIV virus, but delays further damage to the immune system by stopping production of new viruses.

Abacavir and lamivudine combination tablets do 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 and lamivudine combination 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.

There is no evidence that this medicine is addictive.

Use in children

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

You must not take this medicine if:

- **You have a serious liver disease, this medicine may not be suitable for you.**
- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

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 (Trizivir & Ziagen) 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 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 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 of your unused abacavir and lamivudine combination tablets to your doctor or pharmacist for proper disposal.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - abacavir and lamivudine combination tablets or other abacavir containing products (Ziagen & Trizivir)
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - hepatitis B
 - a heart attack or you are considered at a high risk of having a heart attack.

3. You are currently pregnant or you plan to become pregnant. Do not take this medicine until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine until you and your doctor have discussed the risks and benefits involved.
5. You have recently been vaccinated or plan to get a vaccination.
6. You are planning to have surgery or an anaesthetic.
7. You are currently receiving or are planning to receive dental treatment.
8. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available 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).

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 any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with abacavir and lamivudine.

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.

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.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Abacavir and lamivudine combination tablets should be swallowed whole with water.

Abacavir and lamivudine combination tablets do not have to be taken with food.

When to take it

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

It does not matter if you take it before, with or after food.

How long to take it for

Your medicine helps to control your condition, but does not cure it, so you will need to take your tablets every day. Continue taking your medicine for as long as your doctor tells you.

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 missed dose and take your next dose at the usual time. 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 missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your

pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

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.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you plan to have any vaccinations or immunisations
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.

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.

No studies on the effects of abacavir and lamivudine combination 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 and lamivudine combination tablets before considering driving or using machines.

Possible 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 and lamivudine combination tablets, even if the problem is not listed in this leaflet.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Hypersensitivity Reaction

A hypersensitivity reaction (serious allergic reaction) has been reported in about five in every hundred patients who have been treated with abacavir and lamivudine combination tablets. 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 common side effects:

- 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)

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

These may be serious side effects and you may need medical attention:

Uncommon:

- increases in enzymes produced by the liver
- anaemia (low red blood cell count)
If the production of red blood cells is reduced, 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)

Rare:

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

Very rare:

- 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.

If you experience the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- **lactic acidosis**
If you become very sick, with fast breathing you may have a condition known as "lactic acidosis". The fast breathing is due to high acid levels in the blood. This can be life-threatening. This illness occurs more often in women than men.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to abacavir and lamivudine, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic (anaphylactic) reaction, which may occur soon after starting this medicine may include some or all of the following:

- 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
- fainting
- hay fever-like symptoms.

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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

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.

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.

Australian Registration Numbers

Abacavir/Lamivudine APOTEX 600/300 mg tablet (blister pack) of 30 tablets: AUST R 239753.

Abacavir/Lamivudine APOTEX 600/300 mg tablet (bottle) of 30 tablets: AUST R 239757.

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

Sponsor

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This leaflet was last updated in July 2016