
Abacavir Sulfate and Lamivudine Tablets 600/300mg

Read all of this leaflet carefully before you start taking this medicine.

- 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 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

. IMPORTANT — Hypersensitivity reactions

Abacavir Sulfate and Lamivudine 600/300mg contains abacavir (which is also an active substance in medicines such as Trizivir, Triumeq **and** Ziagen). Some people who take abacavir may develop a hypersensitivity reaction (a serious allergic reaction), which can be life-threatening if they continue to take abacavir containing products. You must carefully read all the information under ‘Hypersensitivity reactions’ in the panel in Section 4.

The Abacavir Sulfate and Lamivudine 600/300mg pack includes an Alert Card, to remind you and medical staff about abacavir hypersensitivity. Detach this card and keep it with you at all times.

What is in this leaflet

- a) What Abacavir Sulfate and Lamivudine Tablets is and what it is used for
- b) What you need to know before you take Abacavir Sulfate and Lamivudine Tablets
- c) How to take Abacavir Sulfate and Lamivudine Tablets
- d) Possible side effects
- e) How to store Abacavir Sulfate and Lamivudine Tablets
- f) Contents of the pack and other information

a) What Abacavir Sulfate and Lamivudine Tablets 600/300mg is and what it is used for

Abacavir Sulfate and Lamivudine 600/300mg is used to treat HIV (human immunodeficiency virus) infection in adults, adolescents and in children weighing at least 25 kg.

Abacavir Sulfate and Lamivudine 600/300mg contains two active ingredients that are used to treat HIV infection: abacavir and lamivudine.

Abacavir Sulfate and Lamivudine Tablets 600/300mg



These belong to a group of anti-retroviral medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs).

Abacavir Sulfate and Lamivudine 600/300mg does not completely cure HIV infection; it reduces the amount of virus in your body, and keeps it at a low level. It also increases the CD4 cell count in your blood. CD4 cells are a type of white blood cells that are important in helping your body to fight infection.

Not everyone responds to treatment with Abacavir Sulfate and Lamivudine 600/300mg in the same way. Your doctor will monitor the effectiveness of your treatment

b) What you need to know before you take Abacavir Sulfate and Lamivudine Tablets

Do not take Abacavir Sulfate and Lamivudine 600/300mg:

- if you are allergic (hypersensitive) to abacavir (or any other medicine containing abacavir — (e.g. Trizivir, Triumeq or Ziagen), lamivudine or any of the other ingredients of this medicine (listed in Section 6)

Carefully read all the information about hypersensitivity reactions in Section 4.

Check with your doctor if you think this applies to you. Do not take Abacavir Sulfate and Lamivudine 600/300mg

Take special care with Abacavir Sulfate and Lamivudine 600/300mg

Some people taking Abacavir Sulfate and Lamivudine 600/300mg or other combination treatments for HIV are more at risk of serious side effects. You need to be aware of the extra risks:

- if you have moderate or severe liver disease
- if you have ever had liver disease, including hepatitis B or C (if you have hepatitis B infection, do not stop Abacavir Sulfate and Lamivudine 600/300mg without your doctor's advice, as your hepatitis may come back)
- if you are seriously overweight (especially if you are a woman)
- if you have a kidney problem

Talk to your doctor if any of these apply to you before using Abacavir Sulfate and Lamivudine 600/300mg. You may need extra check-ups, including blood tests, while you are taking your medicine. See Section 4 for more information.

Abacavir Sulfate and Lamivudine Tablets 600/300mg

Abacavir hypersensitivity reactions

Even patients who don't have the HLA-B*5701 gene may still develop a hypersensitivity reaction (a serious allergic reaction)

Carefully read all the information about hypersensitivity reactions in Section 4 of this leaflet.

Risk of heart attack

It cannot be excluded that abacavir may increase the risk of having a heart attack.

Tell your doctor if you have heart problems, if you smoke, or have other illnesses that may increase your risk of heart disease such as high blood pressure, or diabetes. Do not stop taking Abacavir Sulfate and Lamivudine 600/300mg unless your doctor advises you to do so.

Look out for important symptoms

Some people taking medicines for HIV infection develop other conditions, which can be serious. You need to know about important signs and symptoms to look out for while you are taking Abacavir Sulfate and Lamivudine 600/300mg.

Read the information 'Other possible side effects of combination therapy for HIV' in Section 4 of this leaflet.

Protect other people

HIV infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting other people.

Other medicines and Abacavir Sulfate and Lamivudine 600/300mg

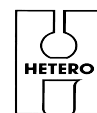
Tell your doctor or pharmacist if you are taking any other medicines, or if you have taken any recently, including herbal medicines or other medicines you bought without a prescription.

Remember to tell your doctor or pharmacist if you begin taking a new medicine while you are taking Abacavir Sulfate and Lamivudine 600/300mg.

These medicines should not be used with Abacavir Sulfate and Lamivudine 600/300mg:

- Emtricitabine, to treat HIV infection
- other medicinal products containing lamivudine, used to treat HIV infection or hepatitis B Infection
- high doses of trimethoprim/sulfamethoxazole, an antibiotic

Abacavir Sulfate and Lamivudine Tablets 600/300mg



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- cladribine, used to treat hairy cell leukaemia

Tell your doctor if you are being treated with any of these.

Some medicines interact with Abacavir Sulfate and Lamivudine 600/300mg

These include:

- phenytoin, for treating epilepsy.

Tell your doctor if you are taking phenytoin. Your doctor may need to monitor you while you are taking Abacavir Sulfate and Lamivudine 600/300mg.

- methadone, used as a heroin substitute. Abacavir increases the rate at which methadone is removed from the body. If you are taking methadone, you will be checked for any withdrawal symptoms. Your methadone dose may need to be changed.

Tell your doctor if you are taking methadone.

Pregnancy

Abacavir Sulfate and Lamivudine 600/300mg is not recommended for use during pregnancy. Abacavir Sulfate and Lamivudine 600/300mg and similar medicines may cause side effects in unborn babies.

If you have taken Abacavir Sulfate and Lamivudine 600/300mg during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child. In children whose mothers took NRTIs during pregnancy, the benefit from the protection against HIV outweighed the risk of side effects.

Breast-feeding

Women who are HIV-positive must not breast-feed, because HIV infection can be passed on to the baby in breast milk. A small amount of the ingredients in Abacavir Sulfate and Lamivudine 600/300mg can also pass into your breast milk.

If you are breast-feeding, or thinking about breast-feeding:

Talk to your doctor immediately.

Driving and using machines

Abacavir Sulfate and Lamivudine 600/300mg may cause side effects which could affect your ability to drive or use machines.

Talk to your doctor about your ability to drive or operate machines while taking Abacavir Sulfate and Lamivudine 600/300mg

Abacavir Sulfate and Lamivudine Tablets 600/300mg



Important information about some of the other ingredients of Abacavir Sulfate and Lamivudine 600/300mg tablets

Abacavir Sulfate and Lamivudine 600/300mg contains a colouring called sunset yellow (E110), this may cause allergic reactions in some people.

c) How to take Abacavir Sulfate and Lamivudine tablets

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

The recommended dose of Abacavir Sulfate and Lamivudine 600/300mg for adults, adolescents and children weighing 25 kg or more is one tablet once a day.

Swallow the tablets whole, with some water. Abacavir Sulfate and Lamivudine 600/300mg can be taken with or without food.

Stay in regular contact with your doctor

Abacavir Sulfate and Lamivudine 600/300mg helps to control your condition. You need to keep taking it every day to stop your illness getting worse. You may still develop other infections and illnesses linked to HIV infection.

Keep in touch with your doctor, and do not stop taking Abacavir Sulfate and Lamivudine 600/300mg without your doctor's advice.

If you take more Abacavir Sulfate and Lamivudine 600/300mg than you should

If you accidentally take too much Abacavir Sulfate and Lamivudine 600/300mg, tell your doctor or your pharmacist, or contact your nearest hospital emergency department for further advice.

If you forget to take Abacavir Sulfate and Lamivudine 600/300mg

If you forget to take a dose, take it as soon as you remember. Then continue your treatment as before.

Do not take a double dose to make up for a forgotten dose.

It is important to take Abacavir Sulfate and Lamivudine 600/300mg regularly, because if you take it at irregular intervals, you may be more likely to have a hypersensitivity reaction.

If you have stopped taking Abacavir Sulfate and Lamivudine 600/300mg

If you have stopped taking Abacavir Sulfate and Lamivudine 600/300mg for any reason — especially because you think you are having side effects, or because you have other illness:

Talk to your doctor before you start taking it again. Your doctor will check whether your symptoms were related to a hypersensitivity reaction. If the doctor thinks they may have been related, you will be told never again to take Abacavir Sulfate and Lamivudine 600/300mg, or any other medicine containing abacavir (e.g. Trizivir, Triumeq or Ziagen). It is important that you follow this advice.

If your doctor advises that you can start taking Abacavir Sulfate and Lamivudine 600/300mg again, you may be asked to take your first doses in a place where you will have ready access to medical care if you need it.

d) Possible side effects

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.

Like all medicines, this medicine can cause side effects, although not everyone gets them.

When you are being treated for HIV, it can be hard to tell whether a symptom is a side effect of Abacavir Sulfate and Lamivudine 600/300mg or other medicines you are taking, or an effect of the HIV disease itself. So it is very important to talk to your doctor about any changes in your health.

Even patients who don't have the HLA-B*5701 gene may still develop a hypersensitivity reaction (a serious allergic reaction), described in this leaflet in the panel headed 'Hypersensitivity reactions'.

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

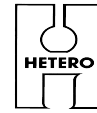
As well as the side effects listed below for Abacavir Sulfate and Lamivudine 600/300mg, other conditions can develop during combination therapy for HIV.

It is important to read the information later in this section under 'Other possible side effects of combination therapy for HIV

Hypersensitivity reactions

Abacavir Sulfate and Lamivudine 600/300mg contains abacavir (which is also an active substance in medicines such as Trizivir, Triumeq and Ziagen). Abacavir can cause a serious allergic reaction known as a hypersensitivity reaction.

These hypersensitivity reactions have been seen more frequently in people taking medicines that contain abacavir.



Who gets these reactions?

Anyone taking Abacavir Sulfate and Lamivudine 600/300mg could develop a hypersensitivity reaction to abacavir, which could be life threatening if they continue to take Abacavir Sulfate and Lamivudine 600/300mg.

You are more likely to develop this reaction if you have a gene called HLA-B*5701 (but you can get a reaction even if you do not have this gene). You should have been tested for this gene before Abacavir Sulfate and Lamivudine 600/300mg was prescribed for you. If you know you have this gene, tell your doctor before you take Abacavir Sulfate and Lamivudine 600/300mg.

About 3 to 4 in every 100 patients treated with abacavir in a clinical trial who did not have the HLAB* 5701 gene developed a hypersensitivity reaction.

What are the symptoms?

The most common symptoms are:

- fever (high temperature) and skin rash.

Other common symptoms are:

- nausea (feeling sick), vomiting (being sick), diarrhoea, abdominal (stomach) pain, severe tiredness.

Other symptoms include:

Pains in the joints or muscles, swelling of the neck, shortness of breath, sore throat, cough, occasional headaches, inflammation of the eye (conjunctivitis), mouth ulcers, low blood pressure, tingling or numbness of the hands or feet.

When do these reactions happen?

Hypersensitivity reactions can start at any time during treatment with Abacavir Sulfate and Lamivudine 600/300mg, but are more likely during the first 6 weeks of treatment

Contact your doctor immediately:

1 if you get a skin rash, OR

2 if you get symptoms from at least 2 of the following groups:

- fever
- shortness of breath, sore throat or cough
- nausea or vomiting, diarrhoea or abdominal pain
- severe tiredness or achiness, or generally feeling ill.

Abacavir Sulfate and Lamivudine Tablets 600/300mg



Your doctor may advise you to stop taking Abacavir Sulfate and Lamivudine 600/300mg

If you have stopped taking Abacavir Sulfate and Lamivudine 600/300mg

If you have stopped taking Abacavir Sulfate and Lamivudine 600/300mg because of a hypersensitivity reaction, you must never again take Abacavir Sulfate and Lamivudine 600/300mg, or any other medicine containing abacavir (e.g. Trizivir, Triumeq or Ziagen). If you do, within hours, your blood pressure could fall dangerously low, which could result in death.

If you have stopped taking Abacavir Sulfate and Lamivudine 600/300mg for any reason — especially because you think you are having side effects, or because you have other illness:

Talk to your doctor before you start again. Your doctor will check whether your symptoms were related to a hypersensitivity reaction. If the doctor thinks they may have been, you will then be told never again to take Abacavir Sulfate and Lamivudine 600/300mg, or any other medicine containing abacavir (e.g. Trizivir, Triumeq or Ziagen). It is important that you follow this advice.

Occasionally hypersensitivity reactions have developed in people who start taking abacavir containing products again, but who had only one symptom on the Alert Card before they stopped taking it.

Very rarely patients who have taken medicines containing abacavir in the past without any symptoms of hypersensitivity have developed a hypersensitivity reaction when they start taking these medicines again.

If your doctor advises that you can start taking Abacavir Sulfate and Lamivudine 600/300mg again, you may be asked to take your first doses in a place where you will have ready access to medical care if you need it.

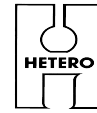
If you are hypersensitive to Abacavir Sulfate and Lamivudine 600/300mg, return all your unused Abacavir Sulfate and Lamivudine 600/300mg tablets for safe disposal. Ask your doctor or pharmacist for advice.

The Abacavir Sulfate and Lamivudine 600/300mg pack includes an Alert Card, to remind you and medical staff about hypersensitivity reactions. Detach this card and keep it with you at all times.

Common side effects

These may affect up to 1 in 10 people:

- hypersensitivity reaction
- headache



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- being sick (vomiting)
 - feeling sick (nausea)
 - diarrhoea
 - stomach pains
 - loss of appetite
 - tiredness, lack of energy
 - fever (high temperature)
 - general feeling of being unwell
 - difficulty in sleeping (insomnia)
 - muscle pain and discomfort
 - joint pain
 - cough
 - irritated or runny nose
 - skin rash
 - hair loss

Uncommon side effects

These may affect up to 1 in 100 people and may show up in blood tests:

- a low red blood cell count (anaemia) or low white blood cell count (neutropenia)
- an increase in the level of liver enzymes
- a decrease in the number of cells involved in blood clotting (thrombocytopenia).

Rare side effects

These may affect up to 1 in 1000 people:

- liver disorders, such as jaundice, enlarged liver or fatty liver, inflammation (hepatitis)
- inflammation of the pancreas (pancreatitis)
- breakdown of muscle tissue.

Rare side effects that may show up in blood tests are:

- increase in an enzyme called amylase.

Very rare side effects

These may affect up to 1 in 10,000 people:

- numbness, tingly feelings in the skin (pins and needles)

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- sensation of weakness in the limbs
 - skin rash, which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (erythema multiforme)
 - a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens–Johnson syndrome), and a more severe form causing skin peeling in more than 30% of the body surface (toxic epidermal necrolysis).
 - lactic acidosis (excess lactic acid in the blood)

If you notice any of these symptoms contact a doctor urgently.

Very rare side effects that may show up in blood tests are:

- a failure of the bone marrow to produce new red blood cells (pure red cell aplasia).

If you get side effects

Tell your doctor or pharmacist if any of the side effects gets severe or troublesome, or if you notice any side effects not listed in this leaflet.

Other possible side effects of combination therapy for HIV

Combination therapy such as Abacavir Sulfate and Lamivudine 600/300mg may cause other conditions to develop during HIV treatment.

Symptoms of infection and inflammation

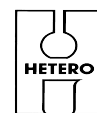
Old infections may flare up

People with advanced HIV infection (AIDS) have weak immune systems, and are more likely to develop serious infections (opportunistic infections). Such infections may have been “silent” and not detected by the weak immune system before treatment was started. After starting treatment, the immune system becomes stronger, and may attack the infections, which can cause symptoms of infection or inflammation. Symptoms usually include fever, plus some of the following:

- headache
- stomach ache
- difficulty breathing

In rare cases, as the immune system becomes stronger, it can also attack 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:

- palpitations (rapid or irregular heartbeat) or tremor



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- hyperactivity (excessive restlessness and movement)
 - weakness beginning in the hands and feet and moving up towards the trunk of the body

If you get any symptoms of infection and inflammation or if you notice any of the symptoms above:

Tell your doctor immediately. Do not take other medicines for the infection without your doctor's advice.

You may have problems with your bones

Some people taking combination therapy for HIV develop a condition called osteonecrosis. With this condition, parts of the bone tissue die because of reduced blood supply to the bone. People may be more likely to get this condition:

- if they have been taking combination therapy for a long time
- if they are also taking anti-inflammatory medicines called corticosteroids
- if they drink alcohol
- if their immune systems are very weak
- if they are overweight.

Signs of osteonecrosis include:

- stiffness in the joints
- aches and pains (especially in the hip, knee or shoulder)
- difficulty moving.

If you notice any of these symptoms:

Tell your doctor.

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

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1

Abacavir Sulfate and Lamivudine Tablets 600/300mg



6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

e) How to store Abacavir Sulfate and Lamivudine Tablets

Keep this medicine out of the sight and reach of children.

Do not take this medicine after the expiry date shown on the carton. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. 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 Abacavir Sulfate and Lamivudine 600/300mg contains

The active substances in each Abacavir Sulfate and Lamivudine 600/300mg film-coated tablet are 600 mg of abacavir (as sulfate) and 300 mg of lamivudine.

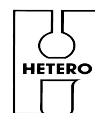
The other ingredients are microcrystalline cellulose, sodium starch glycollate and magnesium stearate in the core of the tablet. The tablet coating contains Opadry Orange YS-1-13065-A containing hypromellose, titanium dioxide, macrogol 400, polysorbate 80 and sunset yellow FCF (E110).

What Abacavir Sulfate and Lamivudine 600/300mg looks like and contents of the pack

Abacavir Sulfate and Lamivudine 600/300mg film-coated tablets are engraved with 'GS FC2' on one side. They are orange and capsuleshaped and are provided in blister packs containing 30 tablets and multipack blister packs containing

90(3 x 30) tablets.

Abacavir Sulfate and Lamivudine Tablets 600/300mg



Hetero

Marketing Authorization Holder

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Manufacturing site

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