

Package leaflet: Information for the patient

Abacavir/Lamivudine 600 mg/300 mg Film-coated Tablets abacavir/lamivudine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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. See section 4.

IMPORTANT — Hypersensitivity reactions

Abacavir/Lamivudine contains abacavir. Some people who take abacavir (or any other medicine containing 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/Lamivudine** pack includes an **Alert Card**, to remind you and medical staff about abacavir hypersensitivity. **Remove this card and keep it with you at all times.**

What is in this leaflet

1. What **Abacavir/Lamivudine** is and what it is used for
2. What you need to know before you take **Abacavir/Lamivudine**
3. How to take **Abacavir/Lamivudine**
4. Possible side effects
5. How to store **Abacavir/Lamivudine**
6. Contents of the pack and other information

1. What **Abacavir/Lamivudine is and what it is used for**

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

This medicine contains two active ingredients that are used to treat HIV infection: abacavir and lamivudine. These belong to a group of anti-retroviral medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs).

It 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 this medicine in the same way. Your doctor will monitor the effectiveness of your treatment.

2. What you need to know before you take **Abacavir/Lamivudine**

Do not take **Abacavir/Lamivudine:**

- if you are **allergic** (*hypersensitive*) to abacavir (or any other medicine containing abacavir — (e.g. abacavir/lamivudine, abacavir/lamivudine/zidovudine, abacavir/dolutegravir/lamivudine), 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 this medicine.**

Warnings and precautions

Take special care with **Abacavir/Lamivudine**

Some people taking abacavir/lamivudine 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 this medicine 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 taking **Abacavir/Lamivudine.** You may need extra check-ups, including blood tests, while you are taking your medicine. **See Section 4 for more information.**

Abacavir hypersensitivity reactions

Even patients who do not 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 this medicine 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/Lamivudine**.

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.

Children

Abacavir/lamivudine should not be given to children who weigh less than 25 kg.

Other medicines and **Abacavir/Lamivudine**

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/Lamivudine.

These medicines should not be used with **Abacavir/Lamivudine:**

- 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
- cladribine, used to treat **hairy cell leukaemia**

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

Some medicines interact with **Abacavir/Lamivudine**

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/lamivudine.
- **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.
- medicines (usually liquids) containing **sorbitol and other sugar alcohols** (such as xylitol, mannitol, lactitol or maltitol), if taken regularly.
Tell your doctor or pharmacist if you are taking any of these.

Pregnancy

Abacavir/Lamivudine is not recommended for use during pregnancy. This medicine may cause side effects in unborn babies. If you have taken abacavir/lamivudine 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 this medicine 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/Lamivudine 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 this medicine.

3. How to take **Abacavir/Lamivudine**

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/Lamivudine for adults, adolescents and children weighing 25 kg or more is one tablet once a day.

Swallow the tablets whole, with some water. This medicine can be taken with or without food.

Stay in regular contact with your doctor

Abacavir/Lamivudine 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 this medicine without your doctor's advice.

If you take more Abacavir/Lamivudine than you should

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

If you forget to take Abacavir/Lamivudine

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 this medicine 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/Lamivudine

If you have stopped taking this medicine 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 this medicine, or any other medicine containing abacavir (e.g. abacavir/lamivudine, abacavir/lamivudine/zidovudine, abacavir/dolutegravir/lamivudine).** It is important that you follow this advice.

If your doctor advises that you can start taking abacavir/lamivudine 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 have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

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.

When you are being treated for HIV, it can be hard to tell whether a symptom is a side effect of abacavir/lamivudine 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 do not 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/lamivudine, 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’.

STOP taking your medicine and contact a doctor immediately if you experience any of the following side effects:

Common (may affect up to 1 in 10 people):

- hypersensitivity (allergic) reactions. Please see the ‘Hypersensitivity reactions’ box below for important information about these symptoms

Hypersensitivity reactions

Abacavir/Lamivudine contains **abacavir** (which is also an active substance in medicines such as abacavir/lamivudine, abacavir/lamivudine/zidovudine, abacavir/dolutegravir/lamivudine). 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/Lamivudine** could develop a hypersensitivity reaction to abacavir, which could be life threatening if they continue to take this medicine.

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/Lamivudine** was prescribed for you. **If you know you have this gene, tell your doctor before you take this medicine.**

About 3 to 4 in every 100 patients treated with abacavir in a clinical trial who did not have the HLA-B*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, shortness of breath, cough, severe tiredness, generally feeling ill, headaches, pains in the muscles.

Other symptoms include:

Pains in the joints, mouth ulcers, sore throat, chest pains, difficulty breathing (respiratory problems), swelling of arms or legs, swollen glands (neck, arm or groin), low blood pressure, inflammation of the eye (conjunctivitis), tingling or numbness of the hands or feet. Signs of liver problems include yellowing of the skin and whites of the eyes, dark urine, light stools and signs of kidney problems include producing little or no urine or lower back pain. Liver and kidney problems can also be seen in blood tests.

When do these reactions happen?

Hypersensitivity reactions can start at any time during treatment with this medicine, 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

Your doctor may advise you to stop taking Abacavir/Lamivudine.

If you have stopped taking Abacavir/Lamivudine.

If you have stopped taking this medicine because of a hypersensitivity reaction, **you must NEVER AGAIN take it, or any other medicine containing abacavir (e.g. abacavir/lamivudine,**

abacavir/lamivudine/zidovudine, abacavir/dolutegravir/lamivudine). If you do, within hours, your blood pressure could fall dangerously low, which could result in death.

If you have stopped taking **Abacavir/Lamivudine** 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 this medicine or any other medicine containing abacavir (e.g. abacavir/lamivudine, abacavir/lamivudine/zidovudine, abacavir/dolutegravir/lamivudine)**. 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/lamivudine 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 this medicine, return all your unused tablets for safe disposal. Ask your doctor or pharmacist for advice.

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

Rare (may affect up to 1 in 1,000 people):

- swelling of the eyelids, face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing

Contact your doctor as soon as possible if you experience any of the following side effects:

Uncommon (may affect up to 1 in 100 people):

- reduced number of white cells, as shown in blood tests, which increases the risk of infections (neutropenia, lymphopenia)
- reduced number of platelets, as shown in blood tests, which causes unexpected bruising or bleeding for longer than normal (thrombocytopenia)

Rare (may affect up to 1 in 1000 people):

- liver disorders, such as jaundice, enlarged liver or fatty liver, inflammation (hepatitis). You may feel sick, notice yellowing of the skin and whites of the eyes, have pale stools, dark urine and severe stomach pain
- inflammation of the pancreas (pancreatitis). You may experience severe pain in the stomach that radiates into the back, have a swollen and tender stomach and feel sick and generally unwell
- breakdown of muscle tissue (rhabdomyolysis). You may have muscle pain, especially in the shoulders, thighs or lower back, weakness or trouble moving arms or legs, dark urine and reduced or no urine

Very rare (may affect up to 1 in 10,000 people):

- deep, rapid, difficult breathing, drowsiness, numbness or weakness in the limbs, feeling sick (nausea), being sick (vomiting) and stomach pain. These may be signs of excess lactic acid in the blood (lactic acidosis), as shown in blood tests
- a failure of the bone marrow to produce new red blood cells (pure red cell aplasia), as shown in blood tests. You may feel tired, lethargic and notice abnormal paleness of the skin
- 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)
- numbness, tingly feelings in the skin (pins and needles)

Other possible side effects:

Common (may affect up to 1 in 10 people):

- headache
- 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 (may affect up to 1 in 100 people):

- a low red blood cell count (anaemia), as shown in blood tests
- an increase in the level of liver enzymes, as shown in blood tests

Rare (may affect up to 1 in 1,000 people):

- increase in an enzyme called amylase, as shown in blood tests

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/lamivudine 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
- 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 via HPRC Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store **Abacavir/Lamivudine**

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

Do not use this medicine after the expiry date which is stated on the carton, bottle label or blister after 'EXP'. The expiry date refers to the last day of that month.

Bottle only: Write the date the bottle was opened on the label and/or carton in the space provided. Do not use this medicine after 90 days of first opening.

This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from light.

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/Lamivudine** contains

The active substances in each film-coated tablet are abacavir sulfate equivalent to 600 mg of abacavir and 300 mg of lamivudine.

The other ingredients in the core of the tablet are microcrystalline cellulose, crospovidone, magnesium stearate, colloidal anhydrous silica and talc. The tablet coating contains hypromellose, titanium dioxide (E171), macrogol and polysorbate 80.

What **Abacavir/Lamivudine** looks like and contents of the pack

A white, oblong, biconvex, film-coated tablet, marked with 'AL12' on one side and 'M' on the other side.

Abacavir/Lamivudine are supplied in plastic bottles with white opaque child-resistant closures containing 30 tablets or blister packs containing 30, 30x1 (perforated unit dose blisters) or 90 tablets or in multipacks of 90 tablets comprising 3 cartons, each containing 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Generics [UK] Limited, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

Manufacturers

Mylan Hungary Kft, Mylan utca 1, Komárom, 2900, Hungary

McDermott Laboratories Limited t/a Gerard Laboratories t/a Mylan Dublin, 35/36 Baldoye Industrial Estate, Grange Road, Dublin 13, Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Abacavir/Lamivudin Vale 600 mg/300 mg Filmtabletten
Belgium tabletten	Abacavir/Lamivudine Vale Pharmaceuticals 600 mg/300 mg filmomhulde
Bulgaria	Abacavir/Lamivudine Vale 600 mg/300 mg film-coated tablets

Croatia	Abakavir/Lamivudin Vale 600 mg/300 mg filmom obložene tablete
Czech Republic	Abakavir/Lamivudin Vale
Denmark	Abakavir/Lamivudin Vale
Estonia	Abakaviir/Lamivudiin Vale
Finland	Abakavir/Lamivudin Vale
France	ABACAVIR/LAMIVUDINE VALE 600 mg/300 mg comprimé pelliculé
Germany	Abacavir/Lamivudin Vale 600 mg/300 mg Filmtabletten
Greece	Abacavir/Lamivudine Vale 600 mg/300 mg film-coated tablets
Ireland	Abacavir/Lamivudine 600 mg/300 mg Film-coated Tablets
Italy	Abacavir e Lamivudina Vale 600 mg/300 mg
Latvia	Abacavir/Lamivudine Vale 600 mg/300 mg apvalkotās tabletes
Lithuania	Abakaviras/Lamivudinas Vale 600 mg/300 mg plėvele dengtos tabletės
Luxembourg	Abacavir/Lamivudine Vale 600 mg/300 mg comprimés pelliculés
Norway	Abakavir/Lamivudin Vale
Poland	Abacawir + Lamivudine Vale
Portugal	Abacavir/Lamivudina Vale 600 mg/300 mg comprimidos revestidos por película
Romania	Abacavir/Lamivudină Vale 600 mg/300 mg comprimate filmate
Slovak Republic	Abakavir/Lamivudín Vale 600 mg/300 mg, filmom obalené tablety
Slovenia	Abakavir/Lamivudin Vale 600 mg/300 mg filmsko obložene tablete
Spain	Abacavir/Lamivudina Vale 600 mg/300 mg comprimidos
Sweden	Abakavir/Lamivudin Vale
The Netherlands	Abacavir/Lamivudine Vale 600 mg/300 mg filmomhulde tabletten
United Kingdom	Abacavir/Lamivudine Vale 600 mg/300 mg Film-coated Tablets

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